for CDER (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; and 76 FR 19376, April 7, 2011) is amended to reflect the restructuring of CDER that was approved by the Secretary of Health and Human Services on May 25, 2011. This reorganization is explained in Staff Manual Guide 1264.31, 1264.36, 1264.37, 1264.38, and 1264.39, and includes the establishment of the Division of Bioequivalence II, Division of Microbiology, Division of Clinical Review, and Division of Chemistry IV. In addition, CDER is retitling the Division of Bioequivalence to the Division of Bioequivalence I.

II. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of Food and Drugs or the Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Person interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20859 Filed 8–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Philadelphia District Office, in co-sponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRB, and research sponsors.

Date and Time: The public workshop will be held on November 16 and 17, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Philadelphia City Center Hotel, 201 North 17th St., Philadelphia, PA 19103, 1–215–448–2000.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $159 plus applicable taxes (available until November 1, 2011, or until the SoCRA room block is filled).

Contact: Anne Johnson, Food and Drug Administration, Philadelphia District, 900 U.S. Customhouse, Second & Chestnut Streets, Philadelphia, PA 19106, 215–597–4390, FAX: 215–597–4660, e-mail: *anne.johnson@fda.hhs.gov*; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 1–800–762–7292 or 215–822–8644, FAX: 215–822–8633, e-mail: *SoCRAmail@aol.com,* Web site: *http://www.SoCRA.org.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Registration: The registration fee covers the cost of actual expenses, including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of registration is as follows:

COST OF REGISTRATION

SoCRA member	($575.00)
SoCRA nonmember (includes membership)	($650.00)
Federal Government member	($450.00)
Federal Government nonmember	($525.00)
FDA Employee	(free) Fee Waived

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this educational activity for a maximum of 13.3 Continuing Education Credits for SoCRA CE and Nurse CNE. SOCRA designates this live activity for a maximum of 13.3 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation. CME for Physicians: SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: SoCRA is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and e-mail, along with a check or money order payable to ''SoCRA''. Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see *Contacts*).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; (12) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research); (15) Are We There Yet? An Overview of the FDA GCP Program.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) as outreach activities by Government Agencies to small businesses.

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20858 Filed 8–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Hemoglobin Standards and Maintaining Adequate Iron Stores in Blood Donors; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Hemoglobin Standards and Maintaining Adequate Iron Stores in Blood Donors.'' The purpose of this public workshop is to discuss blood donor hemoglobin and hematocrit qualification standards in the United States, its impact on donor safety and blood availability, and potential measures to maintain adequate iron stores in blood donors. The public workshop has been planned in partnership with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health, the National Heart, Lung and Blood Institute, America's Blood Centers, AABB, and the Plasma Protein Therapeutics Association. This public workshop will include presentations and panel discussions by experts knowledgeable in the field from academic institutions, government agencies, and industry.

Dates and Times: The public workshop will be held on November 8, 2011, from 8 a.m. to 5:30 p.m. and November 9, 2011, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at the Natcher Conference Center, Main Auditorium, Building 45, National Institutes of Health, 45 Center Dr., Bethesda, MD 20892.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov.*

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers) to Rhonda Dawson (see *Contact Person)* by October 14, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person)* at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Under FDA's current regulations, allogeneic blood donors must have a hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood or a hematocrit value of 38 percent prior to donation (21 CFR 640.3(b)(3) and 640.63(c)(3)). Hemoglobin and hematocrit measurements are typically obtained from a small sample of blood drawn from a finger or vein. New technologies that potentially allow for less invasive, faster, and more convenient methods of measuring blood donor hemoglobin and hematocrit levels are being studied. A low donor hemoglobin and hematocrit level is the most common reason that prospective blood donors, particularly women, are deferred.

Allogeneic donors of a unit of red blood cells generally may not donate more than once in an 8 week period to ensure recovery of their red blood cells and iron stores (21 CFR 640.3). Nonetheless, some donors, especially repeat and premenopausal female donors, can develop iron deficiency, with or without anemia, from blood donation. Improved understanding of iron loss in blood donors may help reduce donor deferrals due to low hemoglobin and hematocrit levels and reduce iron deficiency that can result from blood donation. Different strategies to minimize iron deficiency in blood donors (e.g., testing for iron stores, adjusting the donation interval, or providing iron replacement) have been explored in the past. Changes in qualifying hemoglobin levels have been discussed in various forums for both men and women to bring these levels into closer concordance with population norms. However, the potential risks and benefits of these strategies require further discussion.

This public workshop will serve as a forum for discussion of hemoglobin and hematocrit donation standards, current methods for hemoglobin measurement, iron loss and iron measurement methods in blood donors, and strategies to maintain adequate donor iron stores. The first day of the public workshop will include presentations and panel discussions on the following topics: (1) Hemoglobin standards for blood donors in the United States; (2) studies of hemoglobin distribution and deferral patterns in blood donors; and (3) measurement of hemoglobin and hematocrit and iron levels in blood donors. The second day of the public workshop will include a discussion of the following topics: (1) Iron